DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

DIASORIN INC.
CAROL DEPOUW
REGULATORY AFFAIRS SPECIALIST
1951 NORTHWESTERN AVENUE
STILLWATER MN 55082-0285

December 10, 2014

Re: K141463
Trade/Device Name: LIAISON® XL 1,25 Dihydroxyvitamin D;
LIAISON® XL 1,25 Dihydroxyvitamin D Control Set;
LIAISON® XL 1,25 Dihydroxyvitamin D Calibration Verifiers
Regulation Number: 21 CFR 862.1825
Regulation Name: Vitamin D test system
Regulatory Class: II
Product Code: MRG, JJX
Dated: November 12, 2014
Received: November 13, 2014

Dear Ms. Carol Depouw:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the

electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141463

Device Name
LIAISON® XL 1,25 Dihydroxyvitamin D
LIAISON® XL 1,25 Dihydroxyvitamin D Control Set
LIAISON® XL 1,25 Dihydroxyvitamin D Calibration Verifiers

Indications for Use *(Describe)*
The LIAISON® XL 1,25 Dihydroxyvitamin D is an in vitro chemiluminescent immunoassay (CLIA) intended for the quantitative determination of 1,25 dihydroxyvitamin (1,25(OH)2D) in serum, EDTA and Lithium Heparin plasma. Results of the 1,25 Dihydroxyvitamin D are used in the assessment of vitamin D sufficiency. Assay results should be used in conjunction with other clinical and laboratory data to assist the clinician in making individual patient management decisions in adult populations. The test is to be performed on the LIAISON® XL Analyzer.

The LIAISON® XL 1,25 Dihydroxyvitamin D Control Set is intended for use as assayed quality control samples to monitor the performance of the LIAISON® XL 1,25 Dihydroxyvitamin D assay.

The LIAISON® XL 1,25 Dihydroxyvitamin D Calibration Verifiers are assayed quality control materials intended for the quantitative verification of calibration and reportable range of the LIAISON® XL1,25 Dihydroxyvitamin D assay.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

LIAISON® XL 1,25 Dihydroxyvitamin D
LIAISON® XL 1,25 Dihydroxyvitamin D Control Set
LIAISON® XL 1,25 Dihydroxyvitamin D Calibration Verifiers

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

1. 510(k) Number: K141463

2. Applicant: Carol A. DePouw
DiaSorin Inc.
1951 Northwestern Avenue, Stillwater, MN 55082-0285
Office Number: 651-351-5850; Fax Number: 651-351-5669
Email: carol.depouw@diasorin.com

3. Date: May 30, 2014

4. Proprietary and Established Names:

LIAISON® XL 1,25 Dihydroxyvitamin D
LIAISON® XL 1,25 Dihydroxyvitamin D Control Set
LIAISON® XL 1,25 Dihydroxyvitamin D Calibration Verifiers

5. Regulatory Information:

LIAISON® XL 1,25 Dihydroxyvitamin D

Regulation Section: 21 CFR 862.1825
Classification: Class II
Product Code: MRG
Panel: Clinical Chemistry (75)

LIAISON® XL 1,25 Dihydroxyvitamin D Control Set
LIAISON® XL 1,25 Dihydroxyvitamin D Calibration Verifiers

Regulation Section: 21 CFR 862.1660
Classification: Class I, reserved
Product Code: JJX
Panel: Clinical Chemistry (75)

6. Predicate Devices:

The predicate device used to demonstrate substantial equivalence to the LIAISON® XL 1,25 Dihydroxyvitamin D is the DiaSorin 1,25 Dihydroxyvitamin D ^{125}I RIA previously cleared under k014030.

The predicate device used to demonstrate substantial equivalence to the LIAISON® XL 1,25 Dihydroxyvitamin D is the LIAISON® N-TACT® PTH Gen II Control Set previously cleared under k132515.

The predicate device used to demonstrate substantial equivalence to the LIAISON® XL 1,25 Dihydroxyvitamin D Calibration Verifiers is the LIAISON® N-TACT® PTH Gen II Calibration Verifiers previously cleared under k132515.

7. Device Description:

The LIAISON® XL 1,25 Dihydroxyvitamin D assay is a modified three-step sandwich assay that uses a recombinant fusion protein for capture of the 1,25 $(OH)_2$ D molecule and a murine monoclonal antibody which specifically recognizes the complex formed by the recombinant fusion protein with the 1,25$(OH)_2$ D molecule. Results are determined by a 2 point calibration conversion of the master curve to a working curve. The light signal is measured by a photomultiplier as relative light units (RLU) and is proportional to the concentration of 1,25$(OH)_2$ D present in the calibrators, controls or patient samples.

LIAISON® XL 1,25 Dihydroxyvitamin D Control set contains;

- 2 levels controls containing human serum spiked with 1,25 $(OH)_2$ D, and preservatives; 2 vials each level; lyophilized

The target concentration for control level 1 is 35 pg/mL.
The target concentration for control Level 2 is 120 pg/mL.

The range of concentrations of each control is reported on the certificate of analysis provided with each LIAISON® XL 1,25 Dihydroxyvitamin D Control set.

LIAISON® XL 1,25 Dihydroxyvitamin D Calibration Verifier set contains:

- 4 levels containing human serum spiked with 1,25 $(OH)_2$ D, and preservatives, 1 vial each level, lyophilized

The target concentration for cal verifier A is 15 pg/mL.
The target concentration for cal verifier B is 40 pg/mL.
The target concentration for cal verifier C is 80 pg/mL.
The target concentration for cal verifier D is 150 pg/mL.

The range of concentrations of each calibration verifier is reported on the certificate of analysis provided with each LIAISON® XL 1,25 Dihydroxyvitamin D Calibration Verifier set.

8. Intended Use:

The LIAISON® XL 1,25 Dihydroxyvitamin D is an *in vitro* chemiluminescent immunoassay (CLIA) intended for the quantitative determination of 1,25 dihydroxyvitamin (1,25$(OH)_2$ D) in serum, EDTA and Lithium Heparin plasma. Results

of the 1,25 Dihydroxyvitamin D are used in the assessment of vitamin D sufficiency. Assay results should be used in conjunction with other clinical and laboratory data to assist the clinician in making individual patient management decisions in adult populations. The test is to be performed on the LIAISON® XL Analyzer.

The LIAISON® XL 1,25 Dihydroxyvitamin D Control Set is intended for use as assayed quality control samples to monitor the performance of the LIAISON® XL 1,25 Dihydroxyvitamin D assay.

The LIAISON® XL 1,25 Dihydroxyvitamin D Calibration Verifiers are assayed quality control materials intended for the quantitative verification of calibration and reportable range of the LIAISON® XL1,25 Dihydroxyvitamin D assay.

9. Indication(s) for Use:

Same as Intended Use

10. Substantial Equivalence Information:

The LIAISON® XL 1,25 Dihydroxyvitamin D, LIAISON® XL 1,25 Dihydroxyvitamin D controls and LIAISON® XL 1,25 Dihydroxyvitamin D Calibration Verifiers are prepackaged reagents for use on an automated clinical chemistry analyzer. The DiaSorin 1,25 Dihydroxyvitamin D ^{125}I RIA consists of prepackaged reagents for nonautomated manual use. A comparison of the similarities and differences between the devices are provided in the following table:

Assay Similarities and Differences		
Characteristic	New Device LIAISON® XL 1,25 Dihydroxyvitamin D	Predicate Device 1,25-Dihydroxyvitamin D ^{125}I RIA (K014030)
Intended Use	For *in vitro* quantitative determination of 1,25 Dihydroxyvitamin D	For *in vitro* quantitative determination of 1,25 Dihydroxyvitamin D
Measured Analyte	$1,25(OH)_2$ D	$1,25(OH)_2$ D
Primary extraction	No	Yes
Calibration	Two-point calibration	Five-point calibration
Calibration interval	14 days	every run
Calibrators	2 levels	5 levels
Antibody	Mouse monoclonal	Rabbit polyclonal
Reagent Storage	in refrigerator @ 2-8°C	Same
Measuring range	5 – 200 pg/mL	5 – 200 pg/mL
Sample Matrix	Serum, SST serum, EDTA Plasma, and Lithium Heparin	Serum and EDTA Plasma
Sample size	75 µL	500 µL

Manufacturers Controls	2 levels	Same
Reference range	19.9 – 79.3 pg/mL	25.1 - 66.1 pg/mL

Control Similarities and Differences		
Characteristic	New Device LIAISON® XL 1,25 Dihydroxyvitamin D Control Set	Predicate Device LIAISON® N-TACT® PTH Gen II Control Set (K132515)
Intended Use	intended for use as assayed quality control samples to monitor the performance of the LIAISON® XL 1,25 Dihydroxyvitamin D	intended for use as assayed quality control samples to monitor the accuracy and precision of the LIAISON® N-TACT® PTH Gen II
Storage	Store at 2-8°C until ready to use	Same
Levels	2 levels: lyophilized Level 1 (approx 35 pg/mL) Level 2 (approx 120 pg/mL)	2 levels: lyophilized Level 1 (approx 20 pg/mL) Level 2 (approx 30 pg/mL

Calibration Verifiers Similarities and Differences		
Characteristic	Candidate Device LIAISON® XL 1,25 Dihydroxyvitamin D Calibration Verifiers	Predicate Device LIAISON® N-TACT® PTH Gen II Calibration Verifiers (k132515)
Intended Use	assayed quality control materials intended for the quantitative verification of calibration and reportable range of the LIAISON® XL1,25 Dihydroxyvitamin D assay.	assayed quality control materials intended for the quantitative verification of calibration and reportable range of the LIAISON® N-TACT® PTH Gen II assay
Storage	2 to 8°C	Same
Levels	4 levels; lyophilized Cal Ver A (approx 15 pg/mL) Cal Ver B (approx 40 pg/mL) Cal Ver C (approx 80 pg/mL) Cal Ver D (approx 150 pg/mL)	4 levels; lyophilized Cal Ver A (approx 10 pg/mL) Cal Ver B (approx 150 pg/mL) Cal Ver C (approx 650 pg/mL) Cal Ver D (approx 1600 pg/mL)
Volume	2.0 mLs	Same

11. Standard/guidance Document Reference:

- CLSI Guideline EP5-A2, Evaluation of Precision Performance of Quantitative Measurement Methods;
- CLSI Guideline EP6-A, Evaluation of Linearity of Quantitative Analytical Methods;
- CLSI Guideline EP7-A2, Interference Testing in Clinical Chemistry;
- CLSI Guideline EP09-A3 Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline
- CLSI Guideline EP17-A2 Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures;

CLSI Guideline EP28-A3, Defining, Establishing and Verifying Reference Intervals in the Clinical Laboratory.

12. Performance Characters:

Method Comparison

A method comparison study comparing the LIAISON® XL 1,25 Dihydroxyvitamin D assay to the DiaSorin 1,25-Dihydroxyvitamin D ^{125}I RIAassay was performed on 141 samples following CLSI EP9-A3.

Mean results for the 1,25-Dihydroxyvitamin D ^{125}I RIA assay and the singlicate results for LIAISON® XL 1,25 Dihydroxyvitamin D were plotted. Deming regression analyses were performed on the results across the range of the LIAISON® XL 1,25 Dihydroxyvitamin D assay.

Deming Regression					
n	slope	95% CI	intercept	95% CI	R
141	0.973	0.855 to 1.092	-1.614	-7.475 to 4.248	0.918

Sample Matrix Comparison

Fifty-two (52) matched patient sets of serum, SST serum, EDTA plasma, and Lithium Heparin plasma samples were tested to determine if these sample types provide equivalent results on the LIAISON® XL 1,25 Dihydroxyvitamin D assay. The following results were obtained:

Serum vs.	**Slope**	**95% CI**	**Intercept pg/mL**	**95% CI**	**R^2**
SST Serum	1.011	0.99 to 1.03	-0.285	-1.08 to 0.83	0.9908
EDTA Plasma	1.010	0.98 to 1.04	0.321	-1.15 to 1.64	0.9975
Lithium Heparin	1.0000	0.97 to 1.04	0.1000	-1.24 to 1.31	0.9957

Reference Range

It is recommended that each laboratory establish its own range of expected values.

To assess the expected reference range for the LIAISON® XL 1,25 Dihydroxyvitamin D a study was performed with serum samples from 123 apparently healthy adults aged 21 -75 years of age from mixed ethnic backgrounds (48% dark skinned and 52% light skinned). Samples were collected in the winter (48.8%) and summer (51.2%) from subjects with normal Total Calcium, TSH, and PTH values from the northern, central and southern regions of the U.S. Based on the 95% Reference Interval, the following values were established following CLSI guideline C28-A3.

U.S. Subjects	Median $1,25\ (OH)_2$ D	Observed Range 2.5^{th} to 97.5^{th} Percentile
N=123	47.8 pg/mL	19.9 – 79.3 pg/mL

Precision

Precision testing was performed following CLSI Guideline EP5-A2, Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Second Edition.

A coded panel comprised of 6 frozen serum samples (2 spiked, 4 native samples) 2 lots of LIAISON® XL 1,25 Dihydroxyvitamin D controls (2 levels) and 2 lots of LIAISON® XL

1,25 Dihydroxyvitamin D Calibration Verifiers were tested in the study. The precision panel samples and kit controls were tested on two lots of LIAISON® XL 1,25 Dihydroxyvitamin D in two replicates per run, 2 runs per day for 20 operating days for a total of 160 replicate results per sample. The 20 day results are summarized for the combined reagent lot numbers as sample mean 1,25 $(OH)_2$ D concentration in pg/mL, standard deviations and coefficient of variation (%CV) for Between lot and Total across lots.

Sample ID	n	mean (pg/mL)	Between-Lot		Total (Across Lots)	
			SD	%CV	SD	%CV
Kit Control 1	160	30.9	0.84	2.7%	1.16	3.8%
Kit Control 2	160	122.9	6.09	5.0%	4.36	3.6%
Prec Serum 1	160	23.3	0.05	0.2%	1.53	6.6%
Prec Serum 2	160	38.9	0.63	1.6%	2.20	5.7%
Prec Serum 3	160	52.7	0.64	1.2%	2.65	5.0%
Prec Serum 4	160	76.0	1.33	1.7%	3.13	4.1%
Prec Serum 5	160	137.4	1.91	1.4%	6.55	4.8%
Prec Serum 6	160	193.4	5.53	2.9%	11.34	5.9%
Cal Ver A	160	13.4	0.36	2.7%	0.76	5.7%
Cal Ver B	160	38.9	2.76	7.1%	1.36	3.5%
Cal Ver C	160	78.4	3.37	4.3%	2.82	3.6%
Cal Ver D	160	153.0	1.35	0.9%	5.61	3.7%

The following results were obtained from 1 lot of kit controls and the same 6 serum samples with one kit lot assayed in duplicate in two assays per day over 20 operating days.

Sample ID	mean	Intra-Run		TOTAL (Within-lot)	
		SD	%CV	SD	%CV
KC-1	30.3	0.75	2.5%	1.30	4.3%
KC-2	118.6	3.78	3.2%	4.15	3.5%
PREC-1	23.3	0.91	3.9%	1.81	7.8%
PREC-2	38.4	1.27	3.3%	2.58	6.7%
PREC-3	52.2	1.35	2.6%	2.79	5.3%
PREC-4	75.1	2.08	2.8%	3.40	4.5%
PREC-5	136.1	3.26	2.4%	6.91	5.1%
PREC-6	189.5	5.14	2.7%	11.09	5.9%

Linearity

Dilution Linearity:

One serum sample pool was diluted and analyzed by the LIAISON® XL 1,25 Dihydroxyvitamin D assay following CLSI EP6-A. The results were analyzed by regression of Observed 1,25 $(OH)_2$ D Concentration versus Expected 1,25 $(OH)_2$ D Concentration.

The resulting equation is: Observed 1,25 $(OH)_2$ D = 0.981(Expected) + 0.005;R=0.9994

High Dose Hook Effect

Testing was conducted to determine if the LIAISON® XL 1,25 Dihydroxyvitamin D assay is susceptible to artificially low results in the presence of very high levels of 1,25 $(OH)_2$ D (Hook Effect). A zero sample was spiked with enough 1,25 $(OH)_2$ D to equal concentrations above the assay measuring range of 200 pg/mL.

No hook effect was observed up to 5000 pg/mL of 1,25 $(OH)_2$ D .

Recovery Study

Five (5) high concentration serum samples and 5 low concentration serum samples were analyzed neat on the LIAISON® XL 1,25 Dihydroxyvitamin D assay. Recovery samples were then prepared by mixing defined ratios of the high and low samples and tested in replicates of 5. The observed values were compared to the expected values to determine the % recovery.

Samples	Defined Concentration	Expected pg/mL	Observed pg/mL	% Recovery
High Sample 1 (HS1)	177.4			
2 HS1 : 1 LS1		128.0	121.0	95%
1 HS1 : 1 LS1		102.6	97.3	95%
1 HS1 : 2 LS1		77.2	73.0	95%
Low Sample 1 (LS1)	27.8			
High Sample 2 (HS2)	203.6			
2 HS2 : 1 LS2		151.7	141.6	93%
1 HS2 : 1 LS2		125.0	115.4	92%
1 HS2 : 2 LS2		98.2	89.8	91%
Low Sample 2 (LS2)	46.3			
High Sample 3 (HS3)	181.6			
2 HS3 : 1 LS3		134.2	127.0	95%
1 HS3 : 1 LS3		109.8	101.8	93%
1 HS3 : 2 LS3		85.4	81.7	96%
Low Sample 3 (LS3)	38.0			
High Sample 4 (HS4)	201.6			
2 HS4 : 1 LS4		143.0	137.6	96%
1 HS4 : 1 LS4		112.9	105.4	93%
1 HS4 : 2 LS4		82.7	77.4	94%
Low Sample 4 (LS4)	24.2			
High Sample 5 (HS5)	223.8			
2 HS5 : 1 LS5		158.3	148.4	94%
1 HS5 : 1 LS5		124.6	111.8	90%
1 HS5 : 2 LS5		90.8	85.1	94%
Low Sample 5 (LS5)	25.3			
		Mean Recovery		94%

Analytical Specificity

Cross-Reactivity Studies

CLSI Guideline EP7-A2, Interference Testing in Clinical Chemistry; Approved Guideline; Second Edition.

Controlled studies of potentially cross reacting substances were performed on the LIAISON® XL 1,25 Dihydroxyvitamin D assay at the concentrations listed below.

Cross-Reactant	Spiked Concentration	% Cross Reactivity
1,25 $(OH)_2$ D_3	50 pg/mL	103.4%
1,25 $(OH)_2$ D_2	50 pg/mL	104.8%
Zemplar	100 pg/mL	113%
25(OH)D_3	100,000 pg/mL	<0.1%
25(OH)D_2	50,000 pg/mL	<0.1%
24,25 $(OH)_2$ D_3	50,000 pg/mL	<0.1%
25,26 $(OH)_2$ D_3	50,000 pg/mL	<0.1%
3-epi 25 (OH)D_3	100,000 pg/mL	<0.1%
Vitamin D2	50,000 pg/mL	<0.1%
Vitamin D3	50,000 pg/mL	<0.1%
Sensipar	220,000 pg/mL	<0.1%

Interference Studies

Controlled studies of potentially interfering endogenous substances performed in serum with 1,25 $(OH)_2$ D levels up to 60 pg/mL showed no interference in the LIAISON® XL 1,25 Dihydroxyvitamin D at the highest concentration for each substance listed below.

Drug/Substance	Highest Concentration at which no significant interference (≤ ±10%) was observed
Hemoglobin	300 mg/dL
Bilirubin (conjugated)	40 mg/dL
Bilirubin (unconjugated)	40 mg/dL
Triglycerides	3,000 mg/dL
Cholesterol	400 mg/dL
Albumin	12 g/dL
Uric Acid	20 mg/dL
HAMA	3774 ng/mL
Rheumatoid Factor	7310 IU/mL

Controlled studies of potentially interfering exogenous substances performed in serum with 1,25 $(OH)_2$ D levels up to 60 pg/mL showed no interference in the LIAISON® XL 1,25 Dihydroxyvitamin D at the highest concentration for each substance listed below.

Drug/Substance	Highest Concentration at which no significant interference (≤ ±10%) was observed.
Acetaminophen	20 mg/dL
Acetylsalicylic Acid	65 mg/dL
Salicylic Acid	60 mg/dL
Ibuprofen	50 mg/dL
Biotin	0.1mg/dL
Ascorbic Acid	6 mg/dL
Metaprolol	1.2 mg/dL
Propanolol	0.23 mg/dL
Hydrochlorothiazide	0.6 mg/dL
Furosemide	6 mg/dL
Valproic Acid	57.6 mg/dL
Spironolactone	0.6 µg/mL
Nifedipine	43 µg/dL
Verapamil	216 µg/dL
Losartan Potassium	2.25 µg/mL
Valsartan	11 µg/mL
Tetracycline	15.1 µg/mL
Enalapril	42.4 µg/dL
Doxycycline	34.6 µg/mL
Lisinopril	32.7 µg/dL

Limit of Blank, Limit of Detection and Limit of Quantitation

The Limit of Blank, Limit of Detection and Limit of Quantitation were determined according to CLSI EP17-A2: Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline June 2012 - Second Edition.

The following limits were determined with the LIAISON® XL 1,25 Dihydroxyvitamin D Assay:

LoB	LoD	LoQ
≤ 0.35 pg/mL	0.70 pg/mL	5.0 pg/mL

Stability

Product	Storage Conditions		Claimed stability
Reagent Integral	Open vial	at 2-8°C	28 days
Binding Agent	Open vial	at 2-8°C	2 days
Calibrators	Open vial - Reconstituted	On system/ Room temp	6 hours
	Open vial - Reconstituted	2-8°C	14 days
Calibration curve	N/A	N/A	14 days
Controls	Open vial - Reconstituted	On system/ Room temp	6 hours
	Open vial - Reconstituted	2-8°C	28 days
Calibration Verifiers	Open vial - Reconstituted	On system/ Room temp	6 hours
	Open vial - Reconstituted	2-8°C	28 days

Traceability

The LIAISON® XL 1,25 Dihydroxyvitamin D Calibrators, Controls and Calibration Verifiers are traceable to in-house standards prepared from certified reference material 1α, 25 dihydroxyvitamin D.

Value Assignment

Calibrators

A minimum of 5 vials of each level of calibrator are tested on a minimum of 3 LIAISON® XL Analyzers, in a minimum of 5 assay runs with six replicates per vial resulting in a minimum of 30 individual replicate results per calibrator level for final value assignment.

Controls

A minimum of 10 vials of each level of control are tested on 2 different LIAISON® XL 1,25 Dihydroxyvitamin D assay kit lots on a minimum of 3 LIAISON® XL Analyzers, in a minimum of 5 assay runs with 4 replicates per vial resulting in a minimum of 40 individual replicate results per control level for final value assignment.
Final control ranges are established based on ± 2 Standard Deviations.

Calibration Verifiers

A minimum of 10 vials of each level of calibration verifier are tested on 2 different LIAISON® XL 1,25 Dihydroxyvitamin D assay kit lots on a minimum of 3 LIAISON® XL Analyzers, in a minimum of 5 assay runs with 4 replicates per vial resulting in a minimum of 40 individual replicate results per level for final value assignment.
Final calibration verifier ranges are established based on ± 2 Standard Deviations.

13. Conclusion:

The LIAISON®XL 1,25 Dihydroxyvitamin D is substantially equivalent in principle and performance to the DiaSorin 1,25 Dihydroxyvitamin D ^{125}I RIA. Accuracy was demonstrated by a Method Comparison.

The LIAISON® XL 1,25 Dihydroxyvitamin D Control Set and the LIAISON® XL 1,25 Dihydroxyvitamin D Calibration Verifiers are substantially equivalent in principle and performance to the LIAISON® N-TACT® PTH Gen II Control Set and LIAISON® N-TACT® PTH Gen II Calibration Verifiers, respectively.